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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,620	02/04/2002	Sanna-Maria Kakonen	2328-123	2067

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,620	KAKONEN ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

2. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for assessment of bone fragility and fracture, does not reasonably provide enablement for assessment osteoporosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As set forth in *In re Wands, 858 F .2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The instant invention directs to a method of assessment of bone fragility and fracture, or osteoporosis. Although applicant provides methods and results of the collected data of this study from nearly 800 samples (men= 301; women= 491), nevertheless all the results merely support the notion that certain forms of osteocalcin, e.g. COC, ratio of COC/IOC or COC/TOC, may have correlation to the bone fracture or fragility (See Table 4, 5 and 6). There is no example or data collection for osteoporosis analysis. Particularly, examiner would like to draw applicant's

attention to the teachings of Koyama et al. (J. Immunological Methods (1991) 139: 17-23) where Koyama et al. conducted similar serum COC measurements in both healthy population and osteoporosis patients as recited in the instant invention by using antibodies capable of recognizing specific epitopes on the osteocalcin molecules. Contrast to what had being claimed in this application, i.e. the *lower* of COC concentration is indicative of osteoporosis, Koyama et al. observed conflicting results, i.e. a *higher* COC concentration in osteoporosis patients compared to healthy people (See Abstract; Methods and Materials; Table 3 and 4)(Healthy mean= 3.6 + SD 2.19 ng/ml; Osteoporosis mean 10.1 + SD 4.60 ng/ml). Furthermore, applicant indicates that there exits controversy among scientific communities with respect to the correlation of osteoporosis and the osteocalcin (See page 4, second paragraph). Taken together that lack of clear guidance and instructions given in this application as to direct one skilled in the art how to perform the recited method to evaluate osteoporosis, and the correlation between osteoporosis and osteocalcin remains uncertain, it would inevitably impose undue experimentation burden to skilled artisan to use instant invention in commensurate with the scope recited.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (b)(ii), "the determined ratio COC/IOC or COC/TOC for said person" lacks antecedent basis.

With respect to claim 1, step (b)(ii), line 3, "(mean ratio COC/IOC or mean ratio COC/TOC), is vague and indefinite. It is redundant and confusing. It is suggested that applicant delete this phrase.

With respect to claim 1, step (c), "using" is vague and confusing. It is not clear what applicant meant "using" here.

With respect to claim 9, line 6. "the antigen" lacks antecedent basis.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 9-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koyama et al. (J Immunological Methods (1991) 139: 17).

Koyama et al. teach a method of detecting osteoporosis by use of osteocalcin capturing antibody measuring osteocalcin levels in osteoporosis patients' serum (See Abstract, page 19, Figure 4 and Table III). The detecting reagent of claim 9 corresponds to the enzyme detecting method (EIA) of Koyama et al.. The limitations described for the antibodies of claims 11-15 would appear to be inherently present in the antibodies of Koyama et al., absent evidence to the contrary. The packing of reagents in kit form is an obvious expedient for ease and convenience in assay performance.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

MARY E. CEPERLEY
PRIMARY EXAMINER
Au 1641
Acting SPE

August 6, 2004